UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants, and ELI LILLY AND COMPANY, Intervenor-Defendant.	Case No. 4:24-cv-00953-P

BRIEF *AMICUS CURIAE* OF NOVO NORDISK INC. IN SUPPORT OF DEFENDANTS/INTERVENOR-DEFENDANT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTEREST OF AMICUS CURIAE

Novo Nordisk Inc. ("Novo") is a leading healthcare company, focused on driving change to defeat serious chronic diseases like diabetes and obesity. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic® (semaglutide) injection, Rybelsus® (semaglutide) tablets for adults with type 2 diabetes, and Wegovy® (semaglutide) injection for chronic weight management. Like tirzepatide, semaglutide is a long-half-life glucagon-like peptide-1 receptor agonist ("GLP-1 RA"). This category of medicines activates a receptor that stimulates the release of insulin and slows stomach emptying.

Ozempic® and Wegovy® are the only "two injectable semaglutide products FDA-approved for the U.S. market."[1] Ozempic® is currently indicated for several uses, including use "to improve glycemic control in adults with type 2 diabetes," "to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease," and to reduce the risk of "end stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic

[1] FDA, *Approved Label for NDA 209367* (Jan. 28, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/209637s025lbl.pdf; FDA, *Approved Label for NDA 215256* (Nov. 1, 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215256s021lbl.pdf.

kidney disease."[2] Wegovy® is currently indicated for several uses, including use "to reduce the risk of major adverse cardiovascular events … in adults with established cardiovascular disease" and "to reduce excess body weight" in children and adults ages twelve and older.[3]

Ozempic® and Wegovy® are sought-after and widely used medications that have achieved name-brand recognition across the United States. FDA placed Wegovy® and Ozempic® on the drug shortage list on March 31, 2022 and August 23, 2022, respectively,[4] based on a determination by FDA for each drug that demand or projected demand for certain doses of the drug within the United States exceeded the supply of the drug doses.[5] As of October 30, 2024, FDA listed all presentations of Ozempic® and Wegovy® as fully "available."[6] Nevertheless, both drugs, grouped together as "semaglutide injection," currently are listed by FDA as "in shortage"; Novo believes that FDA should list the shortage as resolved.[7]

Like tirzepatide, semaglutide is currently the subject of widespread knockoffs by drug compounders, like Plaintiffs, who seek to maintain a "shortage" so that they

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[2] *Approved Label for NDA 209367*, *supra* n.1.

[3] *Approved Label for NDA 215256*, *supra* n.1.

[4] FDA, *FDA Drug Shortages, Semaglutide Injection*, (Nov. 1, 2024) "Download Current Drug Shortages," https://perma.cc/Q8S7-D45F.

[5] *See* 21 C.F.R. § 314.81(b)(3)(iii)(f).

[6] *FDA Drug Shortages, Semaglutide Injection*, *supra* n.4.

[7] In September 2023, FDA reorganized the drug shortage database by active ingredient and route of administration, listing Wegovy® and Ozempic® under the group "semaglutide injection."

may continue to produce unsafe, unapproved purported knockoffs of FDA-approved GLP-1 RA medicines.

Novo has a strong interest in ensuring that patients have access to safe, quality, FDA-approved GLP-1 RA medicines and that FDA correctly applies the drug-shortage provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Accordingly, Novo files this brief to provide insights regarding these important issues.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

For decades, FDA's rigorous drug approval regime has been recognized as a global "gold standard." FDA's new-drug-approval process is "long, comprehensive, and costly." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). It requires drug manufacturers to demonstrate—through extensive research and testing over many years—that their medicines are safe and effective under the proposed conditions of use. *See* 21 U.S.C. § 355(d)(4). For example, to obtain FDA approval for its semaglutide injection medicines, Ozempic® and Wegovy®, Novo "undertook over 100 phase II and III clinical trials . . . over the course of more than three decades, collecting more than 135,000 person-years of data."[8] By one "conservative" estimate, Novo "invested well over $10 billion" in research and development.[9] Those efforts resulted in safe and effective medicines that have already benefited millions of patients nationwide.

By contrast, Plaintiffs have not made any remotely comparable investments—through clinical research or otherwise—to demonstrate the safety and efficacy of their compounded knockoff products. They have not obtained FDA approval for those drugs. Instead, Plaintiffs seek to perpetuate a *declared* drug shortage even after the *actual* shortage has been resolved to try to exploit a narrow exception to the statutory

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[8] *See* Testimony of Lars Fruergaard Jørgensen, *Hearing before the S. Comm. on Health, Educ., Labor and Pension* at 11, 118th Cong. (Sept. 24, 2024), https://perma.cc/LK8Y-LJD6.

[9] *Id.*

requirement that a new drug can only be marketed in the United States with FDA's approval.

That gambit should be rejected for what it is—an effort to circumvent the "gold standard" of FDA approval and thereby mass market unsafe and unapproved drugs nationwide, with no end in sight. Plaintiffs' motion for a preliminary injunction to continue a "shortage" that no longer exists rests on a series of factual and legal errors. This brief addresses two of Plaintiffs' most substantial misstatements.

First, Plaintiffs assert (at 2) that "[a]n injunction is required to protect patients." The opposite is true: Patients would likely be *harmed* if this Court were to enjoin FDA's shortage decision and greenlight further compounding. Compounded drugs do not have the same rigorous safety, efficacy, and quality assurances as FDA-approved drugs. For these reasons, FDA has warned that compounded drugs "may expose patients to potentially serious health risks . . . [including] serious patient injury and death."[10] The Agency—like other health regulators, medical professional associations, and obesity advocacy groups—has also explicitly cautioned patients and providers that turning to unapproved versions of GLP-1 RA medicines "can be risky for patients."[11] FDA has observed dosing errors associated with compounded GLP-1

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[10] FDA, *Compounding and the FDA: Questions and Answers* (Nov. 15, 2024), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

[11] FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Dec. 18, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss ("*FDA's Concerns*"); FDA, *FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products* (July (continued…)

RA drugs and counterfeits being marketed to consumers.[12] In addition, compounded GLP-1 RA drugs can pose patient risks because compounders make their knockoff drugs with different methods than approved manufacturers. For example, whereas the semaglutide in Ozempic® and Wegovy® is produced using recombinant DNA technology, the vast majority of compounders use a synthetically-produced alleged version of semaglutide for their knockoff formulations. These processing differences result in different impurity profiles across the products, which can pose significant safety and efficacy risks. Given these risks and uncertainties, medical professionals have called the mass-marketing of compounded GLP-1 RA drugs "the largest uncontrolled, unconsented human experiment of our lifetime."[13]

Second, Plaintiffs accuse FDA of dismissing "evidence" that (Plaintiffs contend) suggests that there is still a tirzepatide shortage. *See* Pls.' Br. 21–23. But virtually all the information that Plaintiffs identify was, as FDA recognized, wholly unreliable. For example, Plaintiffs point to alleged "patient reports," *see* Pls.' Br. 20, but those came from online reporting systems without any meaningful data integrity controls. One platform allowed anyone to report "trouble" getting medication at *any time* "in the past"; collected *no details* regarding the nature of the patient's purported access

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26, 2024), https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded ("*Dosing Errors*").

[12] *FDA's Concerns*, *supra* n.11.

[13] Sam Koppelamn, *et al.*, *Hims & Hers Selling GLP-1 Injection That's Not FDA Approved, From Shady Supplier—And Won't Make You Talk to a Doctor to Get It* (June 27, 2024), https://perma.cc/Z2S6-2T3X.

challenges; and apparently allowed the same individual to submit duplicative reports. Plaintiffs also rely on "screenshots" purporting to show unavailability of approved drugs, but many are undated, lack any information about the would-be buyer, and/or simply show distributor-imposed ordering restrictions. In any event, FDA rightly concluded that localized supply disruptions may exist even when there is not a *nationwide* drug shortage.

This Court should deny Plaintiffs' motion.

ARGUMENT

I. Unapproved compounded GLP-1 RA injectable drugs can pose substantial risks to patients.

"[T]he public interest is disserved by a drug that does not afford adequate protections to its users." *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 253 (5th Cir. 2023), *overruled on other grounds*, 602 U.S. 367, 397 (2024). Patients would be placed at risk if this Court were to enjoin FDA's decision and greenlight exposing patients to further mass compounding of unapproved drugs. An overwhelming body of evidence confirms that compounded drugs—and compounded GLP-1 RA injectable drugs in particular—pose significant risks to the health and wellbeing of patients.

A. Compounded drugs pose distinct safety risks.

As a class, "compounded drugs pose a higher risk than FDA-approved" medicines.[14] As FDA has explained, compounded drugs are not verified for "safety,

[14] FDA, *Compounding when Drugs are on FDA's Drug Shortages List* (Dec. 18, 2024), https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list.

effectiveness or quality," by FDA and thus "may expose patients to potentially serious health risks . . . [including] serious patient injury and death."[15]

Compounded drugs carry distinct risks because they are not subject to rigorous premarket review and approval standards, nor robust post-market monitoring and reporting requirements. Unlike FDA-approved medicines, compounded drugs do not undergo FDA's gold standard, new drug approval process. *See* 21 U.S.C. §§ 353a(a), 353b(a). Among other requirements to obtain FDA approval, manufacturers must show that their medicines are "safe for use" and that there is "substantial evidence that the drug[s] will have the effect [they] purport[] or [are] represented to have." 21 U.S.C. § 355(d)(4); *see also* 21 C.F.R. § 314.125(b). FDA-approved medicines must undergo human clinical trials, across multiple, escalating phases. 21 U.S.C. § 355(d); *Abigail All. for Better Access to Developmental Drugs v. von Esenbach*, 495 F.3d 695, 698 (D.C. Cir. 2007) (en banc). Manufacturers must also submit for FDA's review "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing" of the drug and submit to a premarket inspection if requested by FDA. 21 U.S.C. § 355(b)(1)(A)(iv); 21 C.F.R. § 314.50(d)(1)(ii).[16]

Compounders undergo none of this review. And compounders' finished drugs are subject to little to no post-marketing requirements, including far less extensive—

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[15] *Compounding and the FDA: Questions and Answers*, *supra* n.10.

[16] FDA, *Guidance for Industry: Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER*, 7 (October 2019), https://www.fda.gov/media/131911/download.

if any—pharmacovigilance requirements than FDA-approved medicines.[17] Unlike compounders, manufacturers of approved new drugs must submit detailed post-approval reports including changes to manufacturing techniques, samples of advertising, post-approval studies, and *all* adverse events potentially associated with the medicine—even unserious and expected events. *See* 21 C.F.R. §§ 314.80, 314.81.

The resulting risks flowing from these unapproved, loosely-monitored compounded drugs are not hypothetical. Compounded drugs have been responsible for some of the most serious drug-related public health emergencies in the nation's recent history. In 2012, for example, injectable drugs compounded in Massachusetts and contaminated with fungal meningitis sickened more than 750 patients and killed as many as 100 in the United States.[18] In the aftermath, the Senate Health Committee issued a report finding that "48 other compounding companies were … producing drugs that were either unsafe or were made in unsafe environments." 113 Cong. Rec. S8074 (Nov. 18, 2013).

Although Congress took action in response—passing the Drug Quality and Security Act of 2013 to place further limits on compounders, Pub. L. No. 113-54, 127 Stat. 587 (2013) (codified at various provisions including 21 U.S.C. § 353b)—the risks

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[17] Compounding pharmacies operating under 21 U.S.C. § 353a have *no* adverse event reporting requirements.

[18] U.S. Dep't of Justice, U.S. Att'y's Office, D. Mass, *Former Owner of Defunct New England Compounding Center Resentenced to 14 Years in Prison in Connection with 2012 Fungal Meningitis Outbreak* (July 7, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison-connection-2012.

that compounding poses to the public have endured. In 2017, at least forty-three patients undergoing cataract surgery at a Texas clinic suffered vision loss after receiving postoperative injections of a compounded mixture of steroids and antibiotics.[19] Just last summer, in August 2024, a Pennsylvania-based compounder recalled thousands of vials of compounded semaglutide and tirzepatide that lacked assurances of sterility and had been destined for nationwide distribution to consumers.[20] An inspection revealed significant quality lapses: insects in supposedly sterile areas; drugs of the wrong potency; drugs showing turbidity (a sign of biocontamination); and labels that failed to inform patients that they were receiving unapproved compounded drugs or even to identify the dosage.[21]

B. Compounded GLP-1 RA drugs in particular can pose severe and well-documented safety risks.

The health risks associated with compounded drugs are especially severe when it comes to compounded knockoffs of GLP-1 RA medicines, including tirzepatide and semaglutide. FDA and other health authorities worldwide have repeatedly issued public warnings regarding these dangers. For example, the Australian government

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[19] FDA, *FDA Alerts Health Care Professionals of Adverse Events Associated with Guardian's Compounded Triamcinolone and Moxifloxacin Product for Intravitreal Injection* (July 28, 2017), https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-adverse-events-associated-guardians-compounded-triamcinolone.

[20] FDA, *Enforcement Report—Week of September 11, 2024* (Sep. 11, 2024), https://perma.cc/SBX6-N7HJ.

[21] FDA, *Inspectional Observations of ProRx LLC* (Aug. 2, 2024), https://www.fda.gov/media/182243/download?attachment (containing 13 pages of observed violations).

has banned the compounding of GLP1-RA drugs, including semaglutide and tirzepatide, given the "clear risk to human health."[22] Health regulators in South Africa have warned the public against using compounded GLP-1 RA drugs, citing the risk to patient and the public health posed by substandard compounded formulations of these complex medicines.[23] And at least fourteen state boards of pharmacy or medicine have warned about the dangers of using compounded GLP-1 RA drugs.[24] So

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[22] Press Release, Hon. Mark Butler MP, Gov't of Austl., Dep't of Health and Aged Care, *Protecting Australians from Unsafe Compounding of Replica Weight Loss Products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products?language=en.

[23] Press Release, South African Health Prods. Regul. Auth. (SAHPRA), *SAHPRA's Position on GLP1 and GIP-GLP1 Products That Are Compounded, Substandard and Falsified* (Nov. 8, 2024), https://perma.cc/45AS-USY7. Health regulators in Ireland have similarly warned patients about GLP-1 RA drugs sold online, stating "there can be no guarantees as to what substances these online products actually contain and taking them poses a significant risk to consumers' health." Press Release, Gov't of Ir., Health Prods. Regul. Auth. (HPRA), *HPRA Warns of Health Risks of Semaglutide Type Products Sold Illegally Online* (Nov. 26, 2024), https://perma.cc/L9S6-M53G.

[24] *See* N.J. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Nov. 6, 2023), https://perma.cc/9TF2-KTK3; N.C. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), https://perma.cc/MS5M-TDNS; Miss. Bd. Pharmacy, *Compounded Products Due to Shortage or Due to Special Patient Needs*, https://perma.cc/RW3E-5YHU; Ala. Bd. Pharmacy, *Compounding Semaglutide* (Nov. 2023), https://perma.cc/Z4N6-7YVC; Health Professions Bureau of the Idaho Div. of Occupational and Professional Licenses, *Clinic Dispensing of GLP-1 Products* (May 24, 2024), https://perma.cc/T6LZ-REJD; Kan. Bd. Pharmacy, *Statement on Compounding and Dispensing of Compounded Semaglutide and Other GLP-1 Receptor Agonists* (Apr. 25, 2024), https://www.pharmacy.ks.gov/home/showpublisheddocument/8084/638587069408030000; Ky. Bd. Pharmacy, *Semaglutide Compounding Guidance* (Jun. 2023), https://perma.cc/CKP8-N369; S.D. Bd. Pharmacy, *Beware of Fraud and Counterfeit Popular Weight Loss Products* (Jan. 2024), https://perma.cc/4VUP-WL8S; Oregon Bd. Pharmacy, *Statement on Semaglutide* (Feb. 6, 2025), https://perma.cc/2MGL-H29A; Wash. State Department of Health, *Statement on Compounding Semaglutide* (Aug. 22, 2024), https://perma.cc/B427-6G92; W. Va. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), https://perma.cc/3YPL-EU3D; Meg Farris, (continued…)

have medical professional associations, like the American Diabetes Association: "The ADA recommends against using non-FDA-approved compounded GLP-1 … due to safety, quality, and effectiveness concerns and uncertainty about their content."[25] And leading obesity expert organizations have publicly recommended that patients avoid compounded GLP-1 RA drugs because they "are not the same as the drug provided by the manufacturers" and can pose "serious health risks."[26]

These bans and warnings are grounded in evidence confirming that GLP-1 RA drugs have characteristics that make them particularly risky to compound. GLP-1 RAs belong to a class of molecules called peptides—large, difficult-to-synthesize molecules that interact with the human body in complex ways—which pose unique safety and efficacy concerns when compounded.[27] Notwithstanding these risks, compounders source the active ingredients in these compounded drugs from suppliers that manufacture the active ingredients in ways that differ from the semaglutide in

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Low-cost Weight Loss Drug Banned in La., 4WWL (Apr. 27, 2023), https://perma.cc/QUT9-JVDZ; Miss. Bd. Of Medical Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of Medical Licensure* (Aug. 29, 2023), https://perma.cc/UX8Z-FKRQ; Ala. State Bd. of Medical Examiners, *Declaratory Ruling of the Alabama State Board of Medical Examiners* (Aug. 8, 2024), https://perma.cc/8ALK-4KVA.

[25] Joshua J. Neumiller et al., *Compounded GLP-1 and Dual GIP/GLP-1 Receptor Agonists: A Statement from the American Diabetes Association*, 48 Diabetes Care 177—181 (Feb. 2025), https://perma.cc/HK8D-8HTB.

[26] The Obesity Society, Obesity Action Coalition, & Obesity Med. Ass'n, *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives* (Jan. 9, 2024), https://perma.cc/BV57-CJCP.

[27] *See* FDA, *ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin: Guidance for Industry* (May 2021), https://www.fda.gov/media/107622/download.

FDA-approved versions. For example, Novo manufactures semaglutide for its medicines through recombinant DNA technology based on a polypeptide precursor expressed from yeast—the technique that FDA evaluated when it approved Ozempic® and Wegovy®.[28] But compounders rely on semaglutide produced via a different method: chemical synthesis. FDA has not approved any semaglutide medicines in which the semaglutide was manufactured by chemical synthesis—and this process can introduce new and different impurities.[29]

Even in small quantities, these impurities can negatively and significantly impact the safety and efficacy of a drug product.[30] Immune responses to peptide impurities can include, among others, life-threatening anaphylaxis, fever, rash, tissue inflammation and "central nervous system complications."[31] Furthermore, the neutralizing antibodies created by the immune response to these impurities can lead to a loss of efficacy and therapeutic options: most concerning, after using compounded drugs, a patient's body may reject not only compounded semaglutide, but potentially

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[28] *See* U.S. Patent No. 10,335,462, Use of Long-Acting GLP-1 Peptides; U.S. Patent Appl. 20100317057, Semi-Recombinant Preparation of GLP-1 Analogues; U.S. Patent No. 11,759,501, Compositions of GLP-1 Peptides and Preparation Thereof; European Medicines Agency, *Summary of Ozempic® Assessment Report* (Dec. 14, 2017), https://perma.cc/495Z-HLKL.

[29] Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-on GLP-1 Polypeptide Drugs*, Pharm. Rsch., Table IV at 7–8. (Oct. 8, 2024).

[30] *See ANDAs for Certain Highly Purified Synthetic Peptide Drug Products, supra* n.28, at 2, 4 (acknowledging that, "peptide-related impurities, may affect the safety or effectiveness of a peptide drug product" and increase "the potential for immunogenicity").

[31] FDA, *Guidance for Industry: Immunogenicity Assessment for Therapeutic Protein Products*, 4–5 (Aug. 2014), https://www.fda.gov/media/85017/download.

FDA-approved GLP-1 RA medicines and even naturally-occurring GLP-1.[32] Losing the option to secure treatment from an FDA-approved GLP-1 RA medicine is a severe outcome given the indications for GLP-1 RA medicines like Ozempic®, which reduces the risk of major cardiovascular events, cardiovascular death, and end-stage kidney disease.[33]

In addition, as FDA has warned the public, compounded GLP-1 RA drug products pose "dosing concerns," due to lack of labeling, prescriber and patient error, and compounders offering unapproved dosages.[34] Both FDA and researchers have found "overdoses … associated with compounded semaglutide," involving patients provided with self-injection kits administering doses up to twenty times greater than approved amounts, resulting in hospitalization.[35] In comparison, FDA-approved injectable medicines like Wegovy® and Mounjaro® are sold in pre-filled pens that deliver a preset dose and that bear FDA-approved labeling.[36]

Making matters worse, the widespread false, misleading, and deceptive advertising practices by the compounding industry has made it next to impossible for consumers to understand the differences between approved brand-name medicines

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[32] *See ANDAs for Certain Highly Purified Synthetic Peptide Drug Products, supra* n.28, at 5–6, 8, 21–22, 33–34.

[33] *Approved Label for NDA 209367*, *supra* n.1.

[34] *FDA's Concerns*, *supra* n.11.

[35] *Dosing Errors*, *supra* n.11.

[36] *FDA's Concerns*, *supra* n.11.

and unapproved compounded knockoffs.[37] Consumers are being bombarded by rampant online and other media advertising sponsored by the compounding industry to generate artificial demand for compounded GLP-1 RA drugs, including for unindicated uses like cosmetic weight loss.[38] One study of websites advertising compounded GLP-1 RA drugs found that half failed to disclose warnings, precautions, or contra-indications for compounded GLP-1 RA drugs.[39] Forty percent made unauthorized efficacy claims.[40] And dozens of websites either failed to disclose that the drugs they sold were compounded, or falsely implied that they were FDA-approved brand or FDA-approved generic medicines.[41] In light of these deceptions, the former director of Massachusetts General Hospital's Weight Center has described the mass-marketing of compounded GLP-1 RA's as "the largest uncontrolled, unconsented human experiment of our lifetime."[42] By broadly disseminating

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[37] *See* Ashwin K. Chetty et. al., *Online Advertising of Compounded Glucagon-Like-Peptide-1 Receptor Agonists,* 6 JAMA Health Forum e245018 (Jan. 17, 2025) (finding that eleven websites selling compounded GLP-1s did not disclose the medicines for sale were compounded, seven websites incorrectly stated that compounded GLP-1s were generic, and twenty-nine websites stated or implied these drugs were FDA-approved).

[38] Rena M. Conti, *et al*, *Marketing and Safety Concerns for Compounded GLP-1 Receptor Agonists*, 6 JAMA Health Forum e245015 (Jan. 17, 2025) ("To capitalize on demand, several companies have launched marketing campaigns and have engaged 'patient influencers' to promote weight-loss programs.").

[39] *Online Advertising of Compounded GLP-1*, *supra* n.38.

[40] *Id*.

[41] *Id*.

[42] *Hims & Hers Selling GLP-1 Injection That's Not FDA Approved, From Shady Supplier*, *supra* n.13.

potentially dangerous knockoffs of FDA-approved drugs, compounders put unwitting Americans at risk.

C. Compounders' safety arguments are flawed.

Ignoring the dangers that compounded drugs pose, Plaintiffs and their amicus, Ivim Health, offer misleading arguments about the impact of injunctive relief on patient safety. Plaintiffs claim that FDA has received fewer adverse events reports associated with the compounders' knockoff tirzepatide drugs than the FDA-approved tirzepatide medicines. Pls.' Br. 25. But that comes as no surprise: Because they exist outside of the gold-standard regime, adverse events associated with compounded drugs are chronically underreported, as FDA itself has stated.[43] Unlike sponsors of FDA-approved medicines, compounding pharmacies like Plaintiff FarmaKeio are not required to engage in surveillance, evaluation, or reporting of adverse events to FDA.[44] Outsourcing facilities are only required to report adverse events that are serious and unexpected.[45]

Amicus Ivim Health argues that patients will be harmed by abruptly discontinuing GLP-1 RA medicines. Ivim Br. 14–17. But Ivim's position simply assumes that FDA is wrong that Lilly's supply of tirzepatide medicines "will meet or

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[43] Janet Woodcock and Julie Dohm, *Toward Better-Quality Compounded Drugs — An Update from the FDA*, 377 New Eng. J. Med. 2509, 2510 (2017); *see also FDA's Concerns*, *supra* n.11 ("[I]t is likely that adverse events from compounded versions of these drugs are underreported.").

[44] *FDA's Concerns*, *supra* n.11.

[45] FDA, *Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (Oct. 2015), https://www.fda.gov/media/90997/download.

exceed projected demand." App. 18. Ivim also wrongly claims that in the absence of compounding, patients will turn to counterfeit GLP-1 RA drugs. Ivim Br. 18. Counterfeit GLP-1 RA drugs *are already* being illegally marketed online to unwitting consumers.[46] And the presence of widespread compounding *increases*, rather than mitigates, the risk of patient exposure to counterfeit GLP-1 RA drugs. The heavily-advertised availability of largely unregulated compounded product via online sales platforms confuses patients, who are put in the impossible position of discerning between compounded and counterfeit products.[47] Moreover, Novo has uncovered examples of compounded "semaglutide" containing no semaglutide at all.[48]

II. FDA reasonably declined to credit unreliable data submitted by the compounding industry.

Plaintiffs repeatedly accuse FDA of "waving away" evidence submitted by the compounding industry. Pls.' Br. 4; *see also id.* at 4–6, 19–23. This *ipse dixit* ignores both FDA's reasoning, App. 33–46, as well as the patently apparent deficiencies with Plaintiffs' "evidence."

Under the Administrative Procedure Act, federal agencies must make decisions using reliable, relevant data. Indeed, "it is an agency's duty to establish the

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[46] *FDA's Concerns*, *supra* n.11.

[47] *Marketing and Safety Concerns for Compounded GLP-1*, *supra* n.39 ("[C]ounterfeit products are now entering into the US supply chain. . . . Nearly half of online pharmacies offering semaglutide may be operating illegally, operating nondelivery scams, or providing products that do not meet quality standards.).

[48] *See, e.g.*, Compl. ¶ 9, *Novo Nordisk Inc. v. Brooksville Pharms. Inc.*, No. 8:23-cv-01503 (M.D. Fla. Jul. 6, 2023) ("Defendant markets and sells to patients certain drug products that purport to contain 'semaglutide.'").

statistical validity of the evidence before it prior to reaching conclusions based on that evidence." *St. James Hosp. v. Heckler*, 760 F.2d 1460, 1467 n.5 (7th Cir. 1985); *see also Friends of Boundary Waters Wilderness v. Bosworth*, 437 F.3d 815, 826–28 (8th Cir. 2006) (agency decision that relied on "unreliable and faulty survey data" was arbitrary and capricious). Further, it is arbitrary and capricious for an agency to rely on data that is "irrelevant" to the determination at issue. *Texas v. Becerra*, 575 F. Supp. 3d 701, 721 (N.D. Tex. 2021).

Attacking FDA's determination that tirzepatide is not in shortage, Plaintiffs argue FDA should have ignored national manufacturer data and instead credited a smattering of screenshots, news reports, and selective survey responses purportedly showing that some patients have had difficulty accessing Lilly's FDA-approved medicines. Pls.' Br. 19. FDA reasonably found that this information had "important limitations" that rendered it unreliable. App. 19; *see also* App. 33–46. In any event, uncorroborated compounder-generated information purportedly showing localized supply chain disruptions in no way demonstrates that there is a nationwide shortage of a drug and is thus irrelevant.

A. The compounding industry submissions are unreliable.

Unsurprisingly, most of the information that Plaintiffs cite came directly or indirectly from the compounding industry. App. 33. For example, Hims & Hers, an online telehealth pharmacy, submitted alleged patient "reports" purporting to show patient access problems for approved GLP-1 RA medicines. App. 99–100; App. 133–34. What Hims & Hers doesn't disclose is that, since FDA's shortage declaration, it has been driving significant sales revenue by engaging in rampant, irresponsible

marketing of compounded GLP-1s.[49] Only weeks ago, it ran a minute-long Super Bowl ad for compounded GLP-1 RA drugs (at $15 million for air time alone) that failed to disclose any side effects whatsoever or many of the unique safety risks—like overdose and contamination—posed by compounded drugs.[50] Other submitters, including Plaintiffs, are compounding pharmacies, outsourcing facilities, and trade associations representing their interests. A single compounding pharmacy—like Plaintiff FarmaKeio—can make millions of dollars each month selling compounded tirzepatide under the auspices of FDA's shortage declaration. Pls.' Br. 23.

These members of the compounding industry submitted two main categories of "information" to FDA: (1) purported "patient reports" of consumers being unable "to access name-brand GLP-1" medicines, and (2) screenshots of pharmacy ordering portals depicting "limited availability" of FDA-approved GLP-1 RA medicines. *See*, *e.g.*, App. 98–101. Neither is reliable.

Patient Reports. Plaintiffs rely on "patient reports" gathered by compounders and telehealth companies like Hims & Hers. *See* Pls.' Br. 20; App. 98–101; App. 132–35. For example, Hims & Hers provided reports submitted through an online form that is open to "[a]nyone who has had trouble getting access to a GLP-1 medication in the past." App. 34. All individuals have to do is identify their state of residence and

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[49] Dani Blum, *Millions Will See This Super Bowl Ad. Health Experts (and Two Senators) Aren't Pleased*, N.Y. Times (Feb. 7, 2025) https://www.nytimes.com/2025/02/07/well/hims-hers-health-super-bowl-ad.html.

[50] *Id.*; *see also*, Nick Brinkerhoff, *How Much is a Super Bowl Commercial? Everything to Know About 2025 Ads*, U.S.A. Today, (Feb. 3, 2025), https://perma.cc/5FL2-VG9U ($7–8 million per 30 seconds of airtime).

what GLP-1 RA medicine and dose they "were . . . trying to get."[51] This online reporting system is *not restricted by date*—inviting patients who "had trouble" getting medication anytime "in the past" to submit responses—and it does not collect any date information apart from the date of submission, meaning that a patient's purported difficulty accessing the drug could be based on a now-resolved experience from months or even years in the past. Nor does the system collect any details regarding the nature of the patient's particular access challenges—let alone define what it means to have "trouble accessing" the GLP-1 medication.

FDA reasonably concluded that this information (and similar information) provided an "inadequate," unreliable basis for finding a continued shortage. App. 35. As FDA pointed out, nebulous reports that a patient had trouble accessing FDA-approved GLP-1 RA medicines do not inform the agency "what kind of challenges the individuals actually experienced." App. 35. These reports could easily refer to access barriers irrelevant to demand, like "an inability to get a prescription from a doctor based on the doctor's medical judgment, or an inability to get insurance coverage." App. 35. And, FDA observed, none of the compounders who collected patient reports described "any controls they may have established to ensure the integrity of the data," such as ensuring that individuals did not submit multiple reports, making the "results" potentially biased and unrepresentative. App. 35.

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[51] Hims, *Hims GLP-1 Supply Tracker* (visited Feb. 7, 2025), https://www.hims.com/weight-loss/supply-tracker.

Screenshots. Plaintiffs and others submitted screenshots purporting to show unavailability or ordering restrictions in distributor sales portals. App. 36–37. These screenshots vary widely. Generally, they show search results for FDA-approved GLP-1 RA medicines within online ordering portals where a pharmacy might purchase these medicines. *See*, *e.g.*, App. 138–72. Some show distributor-imposed ordering restrictions. *See*, *e.g.*, App. 154–59 (two-daily cap on tirzepatide products). Others show hundreds of vials of approved medicines for sale. *See*, *e.g.*, App. 149; App. 166–67. Most do not indicate who the would-be buyer is or the nature of their relationship with the distributor. Many are undated. *See*, *e.g.*, App. 168–70.

FDA reviewed these screenshots and explained that they often lacked critical information, like dates. App. 36–37. FDA found that, given these limitations, compounders' screenshots failed to "undermine[] or outweigh[] the information"—national-level data—"provided by Lilly." App. 37. At most, they reflected "disconnected individual 'snapshots' in time," App. 38, submitted by parties with no incentive to include countervailing examples in which FDA-approved medicines were available for purchase. Because FDA properly viewed these compounder-submitted data as unreliable, the agency was *required* not to ground its decision on those submissions.

Other Information. Other data submitted by compounders had similar flaws, which FDA thoroughly considered in its decision memorandum. App. 33–46. For example, FDA explained that it received news "articles and blog posts" from OFA stating that certain GLP-RA medicines are in shortage. App. 38; *see* App. n.99

(identifying OFA as source of news articles reviewed). And Plaintiffs continue to cite some of these articles in their motion. *See*, *e.g.*, App. 67–72. But these press reports—including an October 2024 press statement by a compounder facing a lawsuit from Lilly, and an uncited assertion in an opinion piece in a student newspaper—have none of the hallmarks of reliable sources. And certainly they are not a basis to ignore nationwide manufacturer data showing that supply exceeds demand.

B. Localized supply disruptions do not equal a nationwide shortage.

In addition to being unreliable, the information submitted by the compounding industry is largely irrelevant because it addresses the wrong question. At most, the compounder data indicates that there may have been localized access issues for particular pharmacies and patients. But a drug is only in shortage "when the demand or projected demand for the drug *within the United States* exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2) (emphasis added); *see also* App. 20 (shortage exists when "*on a nationwide level*, across the entire market," "the demand or projected demand for the drug within the United States exceeds the supply of the drug") (emphasis added).

There are many reasons why a drug may be unavailable at particular pharmacy locations even when the drug is broadly available nationwide. For example, wholesalers—which move product between manufacturers and local distributors like pharmacies—may implement allocation processes that apportion product amongst buyers based on several factors, often including previous sales data. These processes can help increase patient access by ensuring that opportunistic buyers do not hoard or arbitrage product. But a distributor-imposed allocation might also mean that

product is unavailable to a specific pharmacy at a particular time: For example, a pharmacy may not be able to get a product on allocation immediately if it has never ordered the product before. This would appear in that pharmacy's distribution portal as though there is no product (or limited product) available, *see*, *e.g.*, App. 138–39 (limiting unknown buyer to two orders of various tirzepatide products); App. 154–59 (same), even while product changes hands to fully meet demand elsewhere in the same market.

For refrigerated product, like pre-filled tirzepatide and semaglutide injections, pharmacies may also have storage limitations that impact their stock on hand, regardless of the amount of supply available in the broader market. App. 35. After all, Lilly's refrigerated tirzepatide medicines come in twelve dosage forms across two brands—meaning that a particular pharmacy may stock a limited variety of dosages simply because it does not have room to carry (and refrigerate) them all at once. App. 35. By relying heavily on anecdotal reports of individual difficulties in obtaining product, the Plaintiff-compounders improperly conflated the inability to purchase GLP-1 RA medicines from a particular local pharmacy at a particular point in time with the unavailability of product in the broader market.

CONCLUSION

Unapproved compounded product generally—and compounded GLP-1 injections particularly—present increased safety risks. And Plaintiffs' purported "evidence" was not evidence of a drug shortage. This Court should deny Plaintiffs' motion for a preliminary injunction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on February 19, 2025, I caused the foregoing document to be filed with the Clerk of the Court of the United States District Court for the Northern District of Texas using the Court's CM/ECF system.

/s/ Trevor Carolan
Counsel for Novo Nordisk Inc.